Title: USAID TB Joint Assessment Team Report

Dates of visit: March 19-23, 2001

Invited Team participants:

1. Dr. Rodolfo Rodriguez Cruz, PAHO (team leader)
2. Dr. Marcos Espinal, WHO
3. Dr. Patricia Paredes (MSH/RPM Plus)
4. Dr. Peter Gondrie (KNCV/Coalition)
5. Dr. Amy Bloom (USAID/W)

Chapter 1: Introduction

The main objective of the team's visit was "to prepare a proposal for a USAID/Santo Domingo two-year strategy to mitigate TB in the Dominican Republic". The purpose of the team's visit was to assist USAID/SD in the review of the new TB activity with the following expected outcomes:

(1) Recommendations to strengthen various components of the TB control program including policy development or reform, case detection by smear microscopy, lab capacity and quality control, drug availability, monitoring and information systems, and directly observed treatment (DOT);
(2) Recommendations regarding geographic focus of USAID supported programs;
(3) Estimation of the quantities of medications required for TB treatment;
(4) Estimation of the resources needed to accomplish the objective;
(5) Provisional monitoring plan, including results and indicators.

The team was expected to delineate:

(1) The nature of the TB problem, including identification of high prevalence areas;
(2) Institutional and donor resources currently being used to combat the problem;
(3) USAID's comparative advantage in light of past experiences with public and private sector partners in health, and coordination at the provincial level for health activities;
(4) Government capacity and political will; resource availability in the DR and probability of sustainability; adequacy of case identification; current application of the DOTS strategy; lab capacity and quality control procedures; adequacy of TB monitoring and surveillance systems; geographic distribution of cases; management of migrant populations (coordination with Haiti); ability of TB commodity (TB drugs and supplies) management system; sustainability of the USAID intervention.

(Please see Annex 1 for full Scope of Work)

To accomplish these goals, the team visited government officials including the Secretary of Public Health, the national PAHO Representative, as well as the proposed national reference laboratory, and several clinics. (Please see Annex 3 for visit agenda, including list of sites/individuals visited).

The team would like to thank USAID/Dominican Republic, particularly Maria Castillo and David Losk, the Representative and staff of WHO/Dominican Republic, Dr. Ivelisse Acosta and her team, and the staff of the health facilities visited for their invaluable cooperation and assistance.

Chapter 2: Team Findings

(1) Monday, March 19

(a) Meeting with mission staff (David Losk, Maria Castillo), the National TB Manager (Ivelissa Acosta), and PAHO epidemiologist (Rosario Cabrera). After an orientation to the mission, Dr. Acosta presented the proposal developed by the NTP in January, in consultation with the PAHO regional advisor for TB in Latin America (Dr. Rodolfo Rodriguez), the local PAHO epidemiologist (Dr. Pedro L. Castellanos), the WHO Geneva TB consultant for Latin America (Dr. Marcos Espinal), and USAID (Dr. David Losk and Lic. Maria Castillo). The team discussed the proposal as well as the overall TB situation in the DR, including recent changes in government personnel. General points made during the presentation included the existence of a long-standing National TB Program (NTP) and a national TB manual, as well as ongoing PAHO support, and new bilateral funding.

The DOTS strategy was first implemented in the DR two years ago and now covers 10% of the country. Unfortunately, data comparing treatment outcomes in the four provinces which implement DOTS and those that use other strategies are not readily available. In fact, the most recent data on TB treatment outcomes are from 1998, prior to the implementation of DOTS. At that time, the treatment success rate in new smear positives was quite low (41%), with 40% of patients not evaluated and 13% categorized as defaulters. These low success rates, coupled with limited DOTS coverage and wide availability of anti-TB drugs (drug supply has not been a problem for the past few years in the DR) has led to a formidable problem of primary multi-drug resistant TB (MDR-TB). In fact, the DR's MDRTB rate of 6.6% is one of the highest in the world.

(2) Tuesday, March 20

(a) Field visit to Valsequillo Clinical Center in Haina. This clinic has had significant challenges in implementing an effective DOTS program due, in large part, to its location in a port city that has high rates of HIV and large numbers of transients/migrants. The DOTS program initiated here is not yet fully developed, and specific problems noted by the TB program include the need for supplies

(e.g., sputum cups, reagents) and better supervision (e.g., more frequent visits, written comments, and transport to clinics). In addition, the team had specific suggestions regarding the need for increased availability of afternoon lab services, and quality control supervision and feedback. On the other hand, treatment success rates were very good and the treatment well supervised; default tracing had also been implemented. The team was also impressed by the local TB team's initiative in gathering community support for supplemental food for TB patients.

(b) Meeting with Dr. Jose Rodriguez Soldevilla, Secretary of Health (SESPAS). Dr. Soldevilla has held this position for about six months, during which time he appointed Dr. Acosta the NTP manager. The Secretary discussed the need to address problems in the context of primary health, and prevention and control strategies, rather than individual crises. In particular, he noted the possibility of using the mandatory internship year (a medical graduate prerequisite to entering private practice) to train new doctors in the DOTS program. He stated that during his own field year, he had seen many TB cases, sensitizing him to the problem and the need to address it aggressively. He also noted that the increase in TB rates mirrored increasing HIV prevalence, and his belief that it was time to address the problem. Overall, he was extremely supportive; he was in full agreement with the strategy under development and the program that Dr. Acosta was creating. In addition, he guaranteed that the program would be able to count on his backing, including the assurance of needed commodities, specifically drug supplies, for at least the next two years. He also stated that the Ministry would reactivate the National Tuberculosis Committee.

(3) Wednesday, March 21

(a) Field visit to Bani, Peravia Province to visit the Provincial Hospital, a DOTS site and a pilot MTCT site. This site has had directly observed TB treatment since 1996, and has had a DOTS program for the past 1½ years. Training of staff (four) in the DOTS strategy was completed in 10/98, prior to program implementation. The strategy has been quite successful; in 1999, the hospital identified 27 new smear positive TB cases (58 total), and cured 25 (93%). The two patients who did not complete therapy were both HIV positive, and died of HIV/AIDS. In 2000, the program identified 65 cases of TB, of which 38 were new smear-positives. Of 16 cases diagnosed in the first months of 2001, six new smear positives have been identified.

The catchment area for the hospital includes 27 health centers and covers approximately 100,000 people. Case finding for TB is passive, but few, if any patients have been referred from either the inpatient or outpatient services. The program also does contact investigations of newly identified patients. In addition, the hospital serves as a diagnostic center for two other clinics that have implemented DOTS. Patients are sent to the hospital for diagnosis and then referred back to the clinic for treatment, with monthly visits to the hospital

laboratory to monitor progress. Some non-health care community leaders have also been successfully involved as observers, and the program believes that this mechanism may be further utilized with health promoters. The program has been extended to one prison that has enrolled two prisoners thus far. This setting has been somewhat problematic however, as there have been reports of medications being withheld as punishment.

A more comprehensive assessment of the laboratory revealed a smear positivity rate of 4.6%. Sixty-three percent of TB suspects submitted three specimens for smear evaluation (as recommended) while 22% had only one specimen evaluated. On a positive note, all patients registered at the clinics during 2001 were also found in the laboratory register.

(b) The team then met with PAHO representative Dr. Socorro Gross and PAHO epidemiologist Dr. Rosario Cabrera. The team had a long discussion with Dr. Gross regarding the role of PAHO in the new USAID project. In particular, the discussion centered on the ability of PAHO to manage the project with current staffing. The main question was whether or not the new epidemiologist (arriving in the next few weeks) would have the time to oversee the project in the detail required, given oversight responsibilities of other programs, the time frame of the project, and the level of expected scrutiny. Dr. Gross was confident that the new epidemiologist would be able to devote the necessary time. She also stated that the Administrative Unit of PAHO had a great deal of experience in project administration and that the technical person would not have to focus his energies on that component. The group agreed to utilize the unit initially, and to reassess the project in three to four months to determine the necessity of additional personnel solely tasked with project administration. To ensure that this system is responsive to possible administration changes, the budget will be defined accordingly. In addition, the group discussed the need to include the TBCTA (TB Coalition for Technical Assistance) and RPM (Rational Pharmaceuticals Program) Plus in the project design.

(c) Meeting with Glenn Wasek of PROLOG/JSI to discuss drug logistics and the Program for Essential Drugs (PROMESE) in the country. Dr. Wasek stated that his experiences have been limited to dealing with PROMESE in emergency situations and may not be generalizable to other circumstances. He also noted that the current system is being reorganized (PROMESE is currently under a special ministry which reports directly to the President) and some responsibilities may be reassigned. Dr. Wasek felt that the drug stock keeping system was relatively good at the national level, but that improvements needed to be made at the local level. He stressed that the potential for success would be greatly enhanced by the rapid development and initiation of a drug tracking system to ensure sustained availability of medications and identified several areas that needed immediate attention:

(1) Forecasting and procurement--which drugs, quantity, arrival dates

(2) Inventory management--flow of goods from center to periphery (minimum and maximum standards)
(3) Logistics MIS (LMIS)--especially at the peripheral level; particular areas of need include systematizing drug forecasting/distribution, drug transport, improved transaction and consumption record keeping, and improved population accessibility.

Dr. Wasek also stated that PROMESE staff is cognizant of their limitations in various aspects of drug procurement and management, and have asked for logistics assistance. He suggested that USAID might avail itself of the PROLOG training center which includes a library of the latest logistics materials, including the complete FPLM curriculum; a training room which can accommodate up to 18 people; and materials to help upgrade the professionalism of logistics in the DR.

(d) The last meeting of the day was with Dr. Luis Montalvo and Jaime de la Rosa of COPRESIDA (Presidential Program on AIDS), Dr. William Hernandez and Maria Isabel Tavares of DIGECITSS (National HIV/AIDS/STI Program), Dr. Eddy Perez CENISMIS (MTCT study) and DIGECITSS, and Dr. Gullermo Gonzalvez of the Malaria Program. The team discussed the need to investigate areas of the NTP and the HIV/AIDS/STI government strategies that might lend themselves to joint planning and program implementation. There was general agreement on the need for coordination and integration of the two programs. In addition, discussions regarding the $20 million World Bank loan (and $5 million Dominican contribution) were initiated. The World Bank is proposing implementation of integrated care units in several regions of the country and is contemplating an additional TB component. In particular, the NTP and the HIV/AIDS teams have discussed utilizing community workers involved in MTCT programs to do active TB case finding in HIV-positive populations. This project however, would not be started for at least two years, and the loan will not include any TB activities until year three, when an HIV/AIDS program is to begin.

(4) Thursday, March 22

(a) Field visit to Las Caobas Center and the National Reference Laboratory. The team met with staff at the Las Caobas Center, including the chief pulmonologist and head of the hospital's TB program. The DOTS program was established approximately 1½ years ago, and has been rather successful. The first year (1999), the clinic diagnosed 42 patients with active TB. That number decreased to 32 (of which 17 were new smear-positives) in 2000, due to fewer referrals and decentralization of the program to two additional clinics in the catchment area. (These clinics send patients to the hospital for diagnosis and care is supervised by the hospital pulmonologist, but treatment followup and reporting is done by the referring clinic.)

The team found that the staff was very knowledgeable about the essentials of the DOTS program, particularly the treatment regimens, but that several areas

needed further work. First, the referral system of the program needs strengthening. Second, registration of patients referred to the hospital for evaluation was substandard. The lab (which had an 18% positivity rate in suspects) was particularly in need of additional training, as judged by quality control references (5 of 10 specimens re-examined were judged false positives).

Analysis of the 1999 patient cohort showed that the treatment success rate was only 55% (6/11), with 27% defaulters (3/11) and 18% transfers (2/11). Of the three defaulters, one returned to the program, one was drug addicted, and one was homeless. These social problems may prove significant challenges for the NTP as it attempts to extend DOTS implementation throughout the country.

The team then split into two groups, one visiting the National Reference Laboratory and the other visiting the Program for Essential Drugs (PROMESE).

1. The team that visited the National Reference Laboratory was told that the lab had changed considerably in the past year. Although the laboratory was founded four years ago, it had been unable to perform the full complement of reference responsibilities (including quality control and resistance monitoring) due to poor or non-existent equipment. As a result, the veterinary laboratory had been used for these purposes. However, during the past year, the Spanish government had significantly contributed to upgrading the laboratory, and only one essential item was still needed. The laboratory is now capable of performing required functions.

The central laboratory evaluated 4607 smears in 2000 (2975 in 1999); 468 were positive. The central team appeared to be well trained and aware of the need to enhance the training of field laboratorians in general laboratory techniques and quality assurance. They also felt that there were insufficient numbers of functioning microscopes (they estimated that they required 50 more for peripheral labs) and reagents (the government has not made reagents available for the past 2 years; reagents during that time have been donated by bilateral agencies and NGOs).

The laboratory team identified two key problems resulting in a poor laboratory quality assurance (QA) program. First, only 25-30% (40/160) of clinics currently send specimens (all positives and 10% of negatives) for evaluation by the central lab. This is largely due to an inability to transport specimens. To address this problem, the lab team has chosen to recreate a quality control cascade (the last administration dismantled this system) by strengthening the provincial labs (8 provinces and 8 in sectors of Santo Domingo) through retraining technicians in essential reference laboratory services including QA. There is concern however, that this process will take time and that additional resources have not yet been identified.

The second problem identified by the team was the high discordance rate (among the labs that did send QA specimens) between the central and peripheral

labs. This was attributed to new and untrained staff in the periphery; the central staff hoped to remedy this problem through an intensive training program in laboratory techniques. This year, the NTP has already trained 300-400 laboratorians in diagnosis, and will hold two more daylong courses this year, one in quality assurance, and one in biosafety.

2. The second team visited Lic. Ana Teresa Oliver, General Supervisor of the Social Program of Pharmacies at PROMESE. She facilitated a discussion with the pharmacists responsible for the country's three warehouses (one for hospitals, one for health centers, and one for rural clinics), and with the individual responsible for overall (drug) quality control. The group confirmed Dr. Wasek's understanding that a fundamental reorganization of the country's drug management system had begun. The current process for drug procurement includes both a "quantification of needs" (the previous year's consumption plus 5%) and a "programming of needs" from vertical programs (utilizing a committee which develops product specifications) which are sent directly to the director of PROMESE. Once authorized, PROMESE then prepares tenders for the following year based on this information. Drugs are then supplied quarterly to PROMESE that in turn sends out quarterly shipments to commodity warehouses. Bids for these medications have historically been restricted to domestic suppliers.

In the future, quantification and product specification (as well as inspection of facilities, regulatory responsibilities, and rural pharmacy personnel training) will be the function of a newly organized committee based at the MOH (SESPAS). PROMESE will only have a purchasing (non-normative) role; it will become the procurement office for the Social Security Institute and the military in addition to the MOH. Internal quality assurance at PROMESE will be limited to quantification procedures; drug samples will be sent to a private lab (INDOTEC) for qualitative assessment, and the pharmacy quality control team will assess the SESPAS facility.

As a result of the increased procurement responsibilities of PROMESE, the number of medications bought by the organization will substantially increase, and the bidding process is expected to include international as well as domestic suppliers. As can be seen in the table below (based on data kindly provided by PROMESE), this change may result in substantial cost savings.

Table 4: comparison of prices of anti-TB drugs, per 1000 tablets in US$, National TB Program DR and the International Dispensary Association (IDA).

ITEM	NTP DR Costs in $	IDA Costs in $
Rifampicin, 300 mg	$ 73.17	$ 41.47
Isoniazid, 300 mg	$ 10.24	$ 7.03
Pyrazinamide, 500 mg	$ 56.40	$ 27.22
Ethambutol, 400 mg	$ 29.21	$ 17.90

Chapter 3: Proposal Discussion.

The team reviewed the proposal developed by the National TB program, USAID/Santo Domingo, PAHO, and WHO. Although the team gave specific suggestions for each section, general suggestions for the proposal include:

(1) Reorganize subsections by dates of initiation, urgency, and relatedness; avoid duplication
~~(2)~~(1) Prioritize activities to be accomplished using the DOTS strategy as the point of reference
~~(3)~~(1) Define prerequisites for initiating activities and expansion of program
~~(4)~~(2) Include training section as a separate component; include logistics training and training for pulmonologists and other professionals in addition to training for program managers, nurses, health care workers, and laboratorians
~~(5)~~(3) Include TB commodity management section as a separate component
~~(6)~~(1) Specify roles for the TBTCA and RPM Plus consultations
~~(7)~~(1) Reformulate indicators to more clearly reflect the program objectives and activities
~~(8)~~(1) Quantify budget in greater detail with the new PAHO epidemiologist
~~(9)~~(1) Delineate ways in which TB control activities should be integrated into the primary health care system
(10) Ensure initiation of effective DOTS program prior to initiation of operations research; priority operations research should focus on drug resistance survey
(11) Ensure priority in HIV positive patients is in detection of active cases rather than preventive treatment.
(12) Define timeline for activities and assessment visits.

Chapter 4: Next Steps

(1) The final draft of the USAID team report will be delivered to USAID/ Santo Domingo by **April 12, 2001**.
(2) The next draft of the project proposal should be delivered to USAID within two weeks of the arrival of the new PAHO epidemiologist.
(3) The assessment team will, at the request of the USAID/SD mission, review the next draft and send comments to USAID within 2 weeks of receipt.
~~(4)~~(1) The assessment team, after receiving the final draft, will develop indicators for the USAID/SD mission, based on the approved project.
~~(5)~~(1) The assessment team will return within 3-4 months after initiation of the project to ensure adherence to agreed procedures and objectives.

Annex 2: General Assessment, National TB Program, Dominican Republic

The Country

The Dominican Republic covers the eastern two-thirds of the island of Hispaniola, between the Caribbean Sea and the North Atlantic Ocean, east of Haiti. The land area is 48,380 km^2. It lies in the middle of the hurricane belt and is subject to severe storms from June to October, occasional flooding, and periodic droughts.

The estimated population as of July 2000 is 8,442,533 of which 2,909,879 (34.5%) are less than14 years old and 4,153,443 (49.2%) are female. The birth rate is 25.15/1000, the mortality rate is 4,72/1000, and the migration rate is 4.04/1000, resulting in a population growth rate of 1.64%. Seventy-three percent of the population is of mixed ethnic heritage, 16% is white and 11% is black.

The GPD per capita is $5,400 (purchasing power parity) with a growth rate of 8.3%. Agriculture provides 13.6% of the GDP, industry (tourism, sugar processing, mining, textiles, cement and tobacco) 30.8%, and services 55.6%. Of the total population, 25% lives below the poverty line. The literacy rate of those over 15 is 82% (in both men and women). The infant mortality rate is 35.9/1,000 live births and life expectancy at birth is 73.2 years (75.4 for females and 71.1 for males).

The country entered a new area after free and open elections in 1996 that ended a century of mostly non-representative rule.

The Program

Tuberculosis is one of the most important public health problems in the Dominican Republic. The estimated annual incidence rate is more than 100 cases per 100,000 population, one of the highest in Latin America. The country began implementation of the DOTS strategy in 1998 in selected health services in four provinces.

Primary resistance to anti-TB drugs is high, with a multi-drug resistance (MDR) rate of 6.6% (Streptomycin 21.1%, Isoniazid 19.8%, Rifampicin 16.2% and Ethambutol 3.6%). Of note, the adult (15-49 years) HIV Rate was estimated at 2.8% at the end of 1999.

The following tables show basic TB statistics for the DR between 1994 and 1999.

Table 1: Notification data National TB Program DR 1995-1999

YEAR	POPULATION	ALL		N+			
		No.	Rate	No.	Rate	Estimated	% detected
1995	7,823,000	4,053	51,8	2,187	28,0	3,872	56.5
1996	7,961,000	6,006	75.4	3,609	45.3	3,941	91.6
1997	8,097,000	5,601	69.2	2,682	33.1	4,060	66.1
1998	8,231,879	4,263	51.8	2,194	26.7	4,127	53.2
1999	8,364,000	5,978	71	3,489	42	4,966	70

N+: New smear positive patients

Table 2: Country categorization (WHO), 1994-1998

YEAR	CATEGORY
1994	1
1995	1
1996	1
1997	1
1998	3

Category 1: Not implementing DOTS and incidence >10/100,000 population.
Category 3: Implementing DOTS in 10 to 90% of the population.

Table 3: Treatment outcome new smear positive patients, 1995-1998

YR	Regist.	Not-ev.	Cured	Compl.	Def.	Fail.	Dead	Trans	Success
1995	2,007	13.7	43.0	21.1	12.6	2.2	4.8	2.6	64.2
1996	3,609	24.3	30.5	40.1	9.1	1.3	2.5	2.1	60.6
1997	2,682	4.2	66.0	18.0	7.8	1.9	0.7	1.5	83.9
1998	2,194	40	30	11	13	2	3	2	41

Treatment outcome data not yet available for patients treated under DOTS.
The treatment regimen for new smear positive patients is 2 RHZE/4R3H3 (two months of Rifampicin, Isoniazid, Pyrazinamide, and Ethambutol, followed by four months of Rifampicin and Isoniazid three times a week).